REMARKS

Claims 1-39 are pending. Claims 1-22, 24, 26 and 29-37 are withdrawn. Claims 40-56 are added herewith. Support for the amendments can be found throughout the specification and in the original claims of the application. No new matter is introduced. Applicants make these amendments without prejudice to pursuing the original subject matter of this application in a later filed application claiming benefit of the instant application, including without prejudice to any determination of equivalents of the claimed subject matter.

Claim Objections

Claims 23, 25, 27 and 28 are objected to as depending from currently withdrawn claims. Applicants have amended claims 23, 25, 27 and 28 to remove such improper dependencies. Applicants request withdrawal of the objection.

Claim Rejections under 35 USC § 102(b)

Claims 23, 25, 27 and 28 are rejected as allegedly anticipated by Suverkrup et al. (US 6,228,381). Applicants traverse.

The examiner asserts that the subject-matter of claims 23, 25, 27, and 28 is anticipated by the patent application US 6,228,381 B1 (Suverkrup et al.). The examiner asserts that US 6,228,381 B1 discloses a pharmaceutical composition in the form of a freeze-dried xerogel. The examiner further alleges that the pharmaceutical composition comprises an active compound which is dissolved and applied drop-wise to the xerogel carrier.

Applicants disagree with the examiner's assertion. US 6,228,381 B1 describes the process for preparing the pharmaceutical composition (presentation form) in column 5, ll. 49-67. According to step b) of this process, the active compound is dissolved or dispersed in a solution of a swellable or water-soluble, hydrophilic polymer. This solution is added drop-wise to a carrier material according to step c). The carrier material is defined in the text section from column 3, l. 54 to column 4, l. 27. It is specified in this text passage that the

carrier is a textile fabric or a plastic film (col. 3, ll. 54-56) and that it has a hydrophobic surface (col. 4, ll. 9-10). The carrier material and the solution containing the polymer and the active compound are subsequently freeze-dried in step d), thereby generating a lyophilizate containing the polymer and the active compound upon the carrier.

This art method differs in several aspects from the method as claimed in the present application. In US 6,228,381 B1 the active compound and the gel-forming polymer are thoroughly mixed so that the active compound is evenly distributed throughout the freeze-dried polymer solution, In contrast, the method of the present invention first generates a dry xerogel (e.g, a freeze-dried hydrogel) and subsequently applies the active compound onto the xerogel. Thus, the active compound is not evenly distributed throughout the xerogel but it is only present on the surface of the xerogel. This difference between the presentation forms of US 6,228,381 B1 and the delivery system of the present invention is reflected in amended claim 23 by the expression *"wherein the active ingredient is applied on dried microdroplets an at least one surface area of the carrier".* Another feature which further distinguishes the subject-matter of amended claim 23 from the disclosure of US 6,228,381 B1 is the usage of microdroplets. While US 6,228,381 B1 discloses that the solution containing the gel-forming polymer and the active compound is added drop-wise to a carrier material, US 6,228,381 B1 is completely silent on the size of such drops.

Summarizing, the delivery system of amended claim 23 is clearly novel over the disclosure of US 6,228,381 B1. For the same reasons, the subject-matter of independent claim 38 is novel over US 6,228,381 BI. The expression *"a pattern of dried microdroplets containing one or more active ingredients"* implies that active ingredient is not evenly distributed throughout the xerogel but is only present in specific spots, namely the dried microdroplets. The remaining claims derive their novelty from their direct or indirect dependency on claim 23 or 38.

For the sake of completeness, it is noteworthy that misinterpretation of US 6,228,381 B1 might have be caused by the different usages of the term *"carrier"* in the present application and in US 6,228,381 BI. In the present application the carrier denotes the dry xerogel, whereas in US 6,228,381 B1 the term "carrier" refers to a hydrophobic backing

material. Said hydrophobic backing material corresponds to some degree to the inert support recited for example in claim 28 of the present application.

Based on at least the foregoing, the cited art fails to teach each and every element of the claimed subject matter and thus fails to anticipate Applicants' claims. Applicants respectfully request withdrawal of the rejection.

Claim Rejections under 35 USC § 103(a)

Claims 23, 25, 27, 28, 38 and 39 are rejected as allegedly obvious in view of Suverkrup et al. (US 6,228,381). Applicants traverse.

The examiner asserts that the subject-matter of claims 23, 25, 27, 28, 38 and 39 is made obvious by US 6,228,381 (Suverkrup et al.). The examiner sees the difference between the subject-matter of claims 38-39 and US 6,228,381 B1 in that claims 38-39 apply the drops in the form of patterns. US 6,228,381 B1 does not disclose such patterns of drops. Allegedly, it would have been obvious for the skilled person to place the active compound onto the xerogel in a regular pattern.

When addressing the obviousness objection based on US 6,228,381 B1, we prefer to not place the emphasis on the feature *"regular pattern"* but rather on the features used for demonstrating novelty as discussed above, In particular, the fact that the active ingredient is applied in microdroplets on at least one surface of the xerogel carrier provides surprising advantages as compared to the pharmaceutical presentation forms of US 6,228,381 B1, in which the active ingredient is evenly dispersed within the gel.

As stated on page 9, ll. 28-30 of the description, the delivery systems of the invention exhibit advantageous release kinetics. As further explained on page 18, ll. 10-18 the release kinetics of the active ingredient may be controlled by choosing the side on which the ingredient is applied. For example, active ingredients applied on the side of a xerogel

that contacts the release medium will be released very fast, whereas active ingredients applied on the opposite side will be released at a controlled, slow rate. It is also contemplated within the present invention to combine these two types of application (see p. 18, ll. 15-18). The delivery systems (presentation forms) of US 6,228,381 B1 do not allow such a control of release kinetics, since the active ingredients are evenly distributed within the dried gel.

Furthermore, applying the microdroplets just on the surface (as in Applicants' claimed subject matter) allows the usage of several sterilization techniques that cannot be used when the active ingredient and the gel-forming polymer are mixed prior to the sterilization steps. As explained on page 5, ll. 13-19 a mixture comprising the active ingredient and the gel-forming polymer cannot be sterilized by filtration due to the presence of the polymer and cannot be sterilized by heat if the active ingredient is a protein or another heat-labile compound.

Moreover, as explained on p. 5, ll., 19-26 it is advantageous to separate the drying process of the hydrogel from the drying of the active ingredient. In particular, it is easier to identify suitable drying conditions for a hydrogel that lacks the active ingredient than for a hydrogel containing the active ingredient, because the physicochemical properties of the active ingredient can be disregarded.

Summarizing, the delivery systems of the present application exhibit several non-obvious advantages over the delivery systems (presentation forms) disclosed in US 6,228,381 B1. Accordingly, the claimed delivery systems are not made obvious by US 6,228,381 B1 or any other prior art document on file.

Based on at least the foregoing, the cited art fails to teach each and every element of the claimed subject matter and thus fails to anticipate Applicants' claims. Applicants respectfully request withdrawal of the rejection.

Double Patenting

Claims 23, 25, 27 and 28 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 22-25, 27-36, 39, and 43-45 of co-pending application No. 11/661,726 in view of Suverkrup et al. (US 6,228,381). Applicants traverse.

Applicants' submit that the claims as herein amended are non-obvious for at least the reasons delineated above. As this rejection is provisional, Applicants request withdrawal of the rejection upon a finding of allowable claims herein.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 66188NAT(50964).

Dated: January 27, 2011

Respectfully submitted,

Electronic signature: /Jeffrey D. Hsi/
Jeffrey D. Hsi
Registration No.: 40,024

Customer No. 21874

EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5569
Attorneys/Agents For Applicant